Processing of Medical Devices: Risk Management and Plausibility Control

50 years Decontamination Sciences
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Berlin at night…

...nice events
Other events...
...may become incidents!
The evidence* of a final event:

* evidence - the available body of facts or information indicating whether a belief or proposition is true or valid

https://en.oxforddictionaries.com/definition/evidence
A risk is the possibility of harmful events.
A risk is the possibility of harmful events… possibly arising from the intended use of a medical device (MD)

Today, a given clinical environment (medically, technically) faces changes as the events of lethal outcomes (duodenoscopy, USA) led to a worldwide discussion about which are the crucial elements of processing of flexible scopes.

- Do we have “critical” procedures in duodenoscopy, bronchoscopy, and/or in the urogenital indications?
- Is “high-level” disinfection enough?
- How can we avoid biofilms which are often detected if work channels are stripped and extracted from the scope?
- How can we measure contamination? By dilution with sterile water or microbial investigation of the brushes?
- Is brushing and flushing efficient enough for cleaning?
The main aim of hygiene is prevention of such events.

Surgical (endoscopical) intervention is event-related. An „event“ for…

- the patient: expectation of minimal invasiveness
- the medical device: frequency of use, misuse, life span
- the variety of accessories: disposable or reusable (valves, brushes, pouch or container)
- its processing processes: countable (t, T) or “narrative” (SOP) parameters
- the staff: personal protective equipment (PPE), skills
- the infected patient: “evidence”
The operator has the responsibility for results

Operator responsibility pertains to all services of a hospital or other health care facility, which includes the processing of medical devices (MD), usually carried out in a Sterile Processing Department (SPD) or Central Sterile Supply Department (CSSD) or Reprocessing Unit for Medical Devices (RUMED).

There is an obligation to actively request/seek out information in order to keep up with current developments.

The delegation of responsibilities (e.g. to service providers) does not affect the responsibility for the results. The onus of control is on the operator, within his stipulated mandate to provide care.

The manufacturer provides the necessary information for use (IFU) and after sales services supporting the customer.
Risk management is a part of quality management

1. Why risk management?

Responsibility
Because an operation is very dangerous for a patient (in this situation he is not a client anymore).

2. Why plausibility control?

Evidence
Because work must be carried out focused, efficiently and purposefully after all (“just do it, or get it done…”).
A risk exists everywhere in life, limiting it is an essential part of reasoned conduit and interaction between humans; to reduce it is a part of the quality management of an organisation, e.g. a hospital.
Sufficient and appropriate medical devices (MD)

Facilities (quality, quantity of equipment)

Training (on the job, hands on, education)

Processing steps (to be described)

Acceptance criteria (parameters or SOP)

Certified process quality (verification & validation)

Processing following norms and guidelines (state of art)
What is a risk?

Risk is the possible negative outcome of taking action or inaction, combined with damages, disadvantages or loss. Also defined as the intentional interaction with uncertainty.

Risk = probability x expected loss

Examples:
- "Fear the risk" or take it into account
- "A big risk" might be the lack of sterility in MD.
- The patient and health facility are “taking a risk”.
- The operator shall “not take any risks”.
- The insurance company “carries the risk”? 
- “Taking into account” and “thinking through the risks” shows responsibility.
Risk management

Risk management is executed in such a way that possible risks are
• identified
• weighed
• eliminated
• or at least minimized
with regard to the patient, the clinical user or a third person.

The way to go about it is to identify and describe occurring problems (e.g. cleanability), transform them into tasks (e.g. assure safety of verified processing steps) and to find solutions (e.g. standard operating procedures - SOP) that can be (and has to be) controlled during the work process.
Risk management

We need parameters for standardization of the production of processed items.

Our means of control are few:
1. Control of standard operating procedures (SOP)
2. Visual-tactile inspection
3. Monitoring physical parameters (time, pressure, temperature, concentration, conductivity) with data loggers or colorimetry (Bowie Dick, ink indicators)
4. Routine testing (verified and validated test system)
5. Organized documentation (in written)
Principles of risk management

- ALARP
- Risk/Benefit
- HACCP
- CIRS
- CAPA
- Standard Operating Procedure (SOP)

Plausible?
Principles of risk management

Corrective and Preventive Actions (CAPA)

Quality management concept for systematic investigation of discrepancies (e.g. failure/deviations) in order to avoid repeated occurrence (“corrective action”) or to prevent the occurrence in advance (“preventive action”).

To ensure that the measures are effective, a systematic study of outages or deviations is essential.

A system could be for example ISO 13485 or ISO 14971 or the ISO 9000 series.
Principles of risk management

Hazard Analysis and Critical Control Points (HACCP)

A critical control point is a point, step or procedure in the whole processing process, at which controls are possible in order to prevent risks arising from the medical device, so as to eliminate or reduce them to an acceptable level.

Through a hazard analysis, potential hazards (= risks) can be identified and plans for countermeasures be drafted. The control points need to be specified and action limits at each point are to be determined.

The critical intervention limit is the maximum or minimum value, that physical, chemical or biological hazards must be checked for, in order to avert or eliminate a threat, or reduce it to an acceptable level.
Principles of risk management

As Low As Reasonably Practicable (ALARP)

In essence, making sure a risk has been reduced. ALARP is about weighing the risk against the sacrifice (cost, effort) needed to further reduce it. The decision is weighted in favour of health and safety because the presumption is that the duty-holder should implement the risk reduction measure. To avoid having to make this sacrifice, the duty-holder must be able to show that it would be grossly disproportionate to the benefits of risk reduction that would be achieved. Thus, the process is not one of balancing the costs and benefits of measures but, rather, of adopting measures except where they are ruled out because they involve grossly disproportionate sacrifices.
Principles of risk management

Risk Benefit Analysis – weighing the goods

In some cases the only way to mitigate a risk may be to do without a specific instrument. We need it, but we cannot clean it properly. The decision to use this instrument requires the residual risks to be balanced against the anticipated benefits of the procedure. Sometimes these judgments can be made only by a qualified medical practitioner with knowledge of the state of health of an individual patient. It is up to the user to judge if infection is possible.

With the help of the IFU and on the basis of the existing medical device he might come to the conclusion that it is better not to use it. Or he makes sure, perhaps even by tests of his own and interpretation of the results, that the risks are bearable, because a method for cleaning is described.
Principles of risk management

Critical Incident Reporting System (CIRS)
Risk documentation can be done by CIRS, a reporting system for anonymous reporting of critical incidents and near-misses as an essential part of quality management. The goal is risk reduction by closing holes in the multi-layered defenses against risks, which are often due to active and latent failures (Swiss cheese model). This is not possible without risk monitoring and testing.
Principles of risk management

Establish responsibility

Who is wearing the helmet?
Plausibility Control

Risk analysis must face plausibility checks in the first place, before planning an (evidence-based) study. The plausibility check is a rough estimate verification of a result, whether something is plausible (acceptable, reasonable) at all. Do the figures make sense? Thus a possible obvious mistake can be detected early on. And sometimes, this is really all it takes! Plausibility checks can be carried out with only minimal effort on the basis of already existing knowledge.

“The absence of evidence is not the evidence of absence”
Plausible:
complex manipulators of robotic surgery are complex in processing.
Plausible: Similar MD pose similar risks
creating MD families
Risk assessment: requirements for grouping into those families to anticipate processing issues of specific MD:

- Which instruments are potentially “problematic”?
- In which way (function, cleanability, sterilization)?
- Which MD requires a manual pre-treatment?
- Which MD must be validated (following a specific protocol)?
- How can they be validated (design of the protocol)?
- Which parameters are known for the different processing steps including mechanically supported “automated” washing and disinfection processes as well as manual aspects?
- Or is it narrative requiring a standard operating procedure?
- Specific protocols shall only include relevant and structured information for documentation.
Endoscope families

Group 1
• with air/water channel
• with an instrument and suction channel
• with/without an additional instrument channel
• with an additional rinsing channel

*Gastroscopes, colonoscopes*

Group 2
• With air/water channels
• With an instrument and suction channel
• With(out) and additional instrument channel
• With(out) Albarrán channel
• With up to 2 steering channels for balloon catheter

*Gastrointestinal tract*

Group 3
• With up to 2 channels, but without channel system in supply tube
• Without channels in the entire endoscope

*Bronchoscopy, Otorhinolaryngology, urology*
When risks lead to damage, it is an event (or evidence)

A measure to lower the existing risk:
leak test following the information for use (IFU) of the manufacturer
Step by step: Hazard analysis and critical control points

- Dry transport
- Dissassembly
- Pre-washing
- Ultrasound
- Automatized Washing
- Drying
- Thermal Disinfection
- Inspection
- Re-washing?
- Repairs?
- Maintenance
- Assembly
- Soft Packaging Containers
- Sterilisation
  - Steam
  - Formaldehyde
  - Ethylene
  - oxide
  - H2O2 „Plasma“
- Clean
- Un-clean
- Recirculation for use

Transport from OR to CSSD

Time (minutes)

5  60  5  15  30-60

Step by step: Hazard analysis and critical control points

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Risk reduction options:

Innovative product solutions for processability of Albarrán mechanism.
Investigating the risks:
Construction of instruments for correct function (and adequate use)

Arthroscopic forceps dismantable (yes/no)

Related to processing unit in the hospitals
Related to MD
Evaluation of risks:
Is there any evidence of contamination?

The proof of protein traces in our clinical multicenter study 1999-2001* showed that 1-2 out of 3 MD showed protein traces in the solution.

Study profile:
Analysis (3 different methods) from the rinsing solution (SDS) after eye examination for particles (and subsequent exclusion from further examination)
6 CSSD (SPD, RUMED) in Germany
6 different instrument design
6 samples each
3 different methods choosen: OPA, modified Biuret, Pseudoperoxydase reaction for hemoglobin

*Fengler Th, Pahlke H, Michels W et al.: Are processed surgical instruments free of protein? Results of a multicenter study on remnants.
… meanwhile we know that cleanability and design of the medical device are connected. It is established knowledge for officials and in regulatory affairs (e.g. TIR 30, USA).
New risks
Innovative MD might enable new surgical therapies. At the same time they might innoculate microorganisms precisely in the midth of the human body (e.g. laparoscopy)
Tasteful impression

Once bitten twice shy:
The MD might become a risk to the patient.
The patient might be a risk for the precious MD.
A process oriented quality concept

What does (re-)processing of medical devices imply?
... MD ready for processing?
Central Sterile Service Department (CSSD)

Analysing risks

All medical products shall be treated as described in Standard Operating Procedures (SOP) to avoid evidence of failure.

Transport
Disassembling
Pre-treatment
Washing
Disinfection
Drying
Maintenance, Care
Control
Packaging
Sterilisation

Visual & tactile inspection
Physical parameters (T, p, t, concentration)

Control:
- Progress (Data logger)
- End result (colorimetry)

Documentation
SOP

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SOP – standard operating procedure
Procedures must be adapted to the task
All methods start manually, and there is no “automated” processing:

The use of automated endoscopy cleaners (AER) is strongly recommended by experts, but the achievable result might be deceptive.

- adaptation of channels might fail
- flow control might be illusory
- contaminated washing chamber
- pump pressure too low
- defective device
- endoscope not validated for the AER
Risky manual activities: 
Processing is „brainy & brawny“ including a lot of manual work!
Risky manual activities:
sometimes „brawny“ (heavy load) but always „brainy“ (know how)
Possible risk: Microorganisms might be pathogenic

Pathogens are substances or organisms that might cause harmful processes in other organisms.

Those are assigned in medicine the property of pathogenicity.

Pathogens can be bacteria, fungi, parasites, viruses or prions.

Not all microorganisms cause diseases but many can potentially do so.
Risk awareness: Protect yourself!

Hygiene is “the science of prevention of diseases and the preservation, promotion and strengthening of health."

It is related to microbiology, infectiology and environment protection.

And circumstances…
(Pre-) Cleaning

Manual
soaking
brushing
flushing
ultrasonic (pre)cleaning
Both cleaning and biocidal action are disinfection

Cleaning, rinsing, biocidal action ("disinfection") and final rinsing with sterile desalinated water have to be executed separately!
MD often have a complex design e.g. flexible scopes

Most critical although semi-critical?
Cleaning AER

„Automated“ Endoscope Reprocessor require correct adaptation and sufficient pump pressure
Information for use (IFU)

Internet information available

Accessories
(e.g. brushes)
Materials, agents and biocompatibility
Processing Information for Flexible Scope

Flexible Endoscope (Fiberscope / Video-Endoscope)

- **Preparation**
  Leakage test, brushing channels, wipe surfaces

- **Cleaning**
  Manually or automated
  max. temperature 65°C !!
  recommended chemicals

- **Disinfection**
  Manual or automated chemical disinfection process

- **Maintenance**
  Clean optical surfaces with 70% alcohol (Ethanol/Isopropyl)
  Leakage test

- **Sterilization**
  Low temperature processes: (IFU)
  H2O2 (STERRAD / STERIS V-PRO), ETO, FA
Transport solutions to lower risks
Ultrasound is very powerful for mobilizing remnants

Before

After
Riesgo de infección:
Humedad restante (condensado) proporciona a los microorganismos la posibilidad de „nadar“
Protocol of a Datalogger for process control…
Validación de procesos es la verificación de propiedades especificadas especificado antes del proceso.
National laws (e.g. HTM 2030)
Operator´s regulations
International guidelines & Recommendations
WHO 2016
http://apps.who.int/iris/bitstream/10665/250232/1/9789241549851-eng.pdf
KRINKO 2012
Standards:
ISO 15883 series on cleaning
EN 16442 Storage cabinets
ISO 17664 (new DIS for voting)
EN 60601 series (electrical safety and cleaning)
Prior arts (state of science & technologies)
- Medical devices have a specific intended use on patients.
- Risks of clinical interventions have to be minimized for the patient.
- Proper handling and correct use are described in the information for use (IFU). The user has standard operating procedures (SOP).
- Medical devices are a precious and expensive investment.
- Correct processing is crucial to enable correct and hygienic function for a longer work life of the flexible endoscope.
- The processing of medical devices is regarded as “fully controllable” and has to be organized faithful. But in fact, insufficient processing cannot be detected easily on flexible scopes.
- Medical devices possibly do not work properly if not clean. Cleaning means disinfection, but disinfectants do not clean!
- “Event-related” handling means therefore a risk assessment.
COMPLETE CIRCLE OF REPROCESSING

ENDOSCOPIC PROCEDURE
BEDSIDE CLEANING
TRANSPORT TIME < 1 HR.
LEAK TEST
MANUAL WASH
HIGH LEVEL DISINFECTION OR STERILIZATION
RINSE & AIR PURGE
TRANSPORT
STORAGE
TRANSPORT TO PROCEDURE
VALVES
TUBING
PATIENT

MICROBES LOG/10

SUCTION CHANNEL
SURFACE

CRE

MOST RESISTANT ORGANISM

Risk of Contamination
Microbe Range
CRE
Most Resistant Organism
Required State
Numerical Reference to Study Results

Failure Results in Contaminated Endoscope
Endoscope Must Not Have a Leak
Washing Must Remove All Biofilm
Endoscope Must Be 100% Free of Damage

Reusable Tubing & Water Bottles (92% Contaminated)
Reusable Valves (56% Contaminated)

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Hygiene is in your hands!
Prevent events.
Hygiene requirements

Requirements to be observed:

- General hygiene requirements
- Requirements for premises, areas, rooms, spaces
- Requirements for machinery & devices
- Requirements for procedures & processes
- Personnel training “on the job” (professional qualification)
- Personnel requirements (personal protective equipment – PPE)
- Requirements for operating material/resources
- Requirements for safety of patient, staff and third parties
- Environmental requirements, logistics and waste management

Processing: Considerations

- One-way flow
Summary:
Risk management - which processes which means?

Problems with processing?
Let’s create tasks!
Looking for solutions… not admiring the problem.

1. Identification of the risk(s)
2. Evaluation of the identified risks
3. Management of risks
4. Supervision of risks
5. Lowering risks
6. Documentation of risks
Surgical Instruments Work Group Berlin
Chirurgie-Instrumenten-AG Berlin
AUGUSTA Hospital – Training center

P.S.
Hospitals used to have graveyards nearby
International FORUM Medical Devices & Processes: 20 years in 2018